

**National Institutes of Health
Small Business Innovation Research (SBIR) Program
Small Business Technology Transfer (STTR) Program**

**6th Annual SBIR/STTR SWIFT
Outreach Tour**

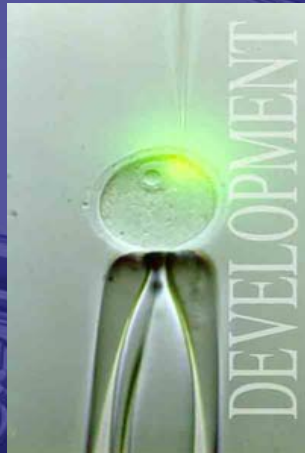
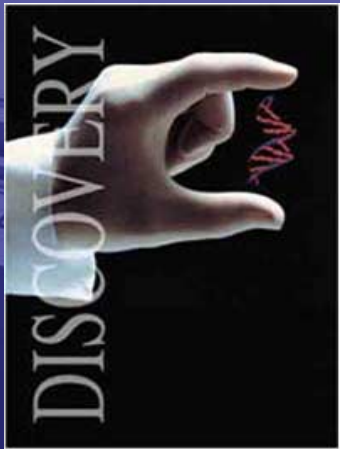
**SBIR Where Innovation Focuses Technology
September 11 - 15, 2006**

Jo Anne Goodnight
NIH SBIR/STTR Program Coordinator
Office of Extramural Research
National Institutes of Health

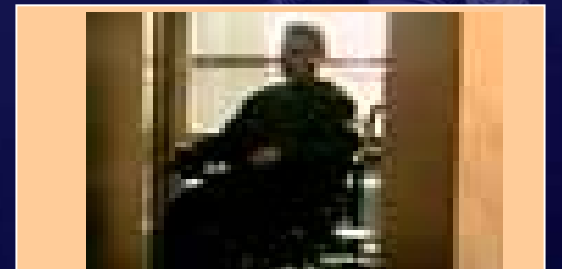
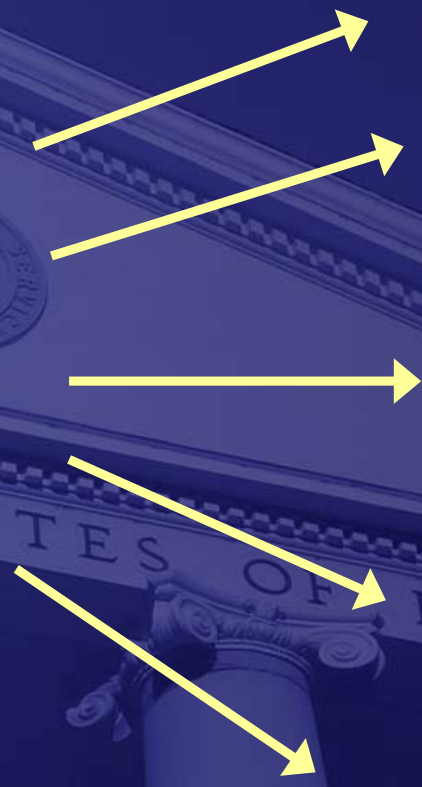


The NIH SBIR Program

Improving the Health of Americans



Transforming medicine
through innovation



NIH Mission

**Improve human health
through biomedical
and behavioral
research,
research training and
communications.**



NIH SBIR/STTR Program

Distinguishing Features

- Investigator-initiated Research
- Award Amount and Project Period
(Reasonable, Appropriate, Justified!)
- Multiple Submission Dates
(New/Amended; Phase I/Phase II)
- Phase II Competing Continuation Awards
- Gap Funding options
- Communication Throughout Process

DHHS Budget and Award Amount

2006 Budget	SBIR	STTR
NIH	\$571M	\$69M
	\$640M	

******Propose a Realistic and Appropriate Budget for the Research******

Take Home Message #1

Phase I	\$100K* 6 months*	\$100K* 1 year*
Phase II	\$750K* 2 years*	\$750K* 2 years*

NIH Organization

Office of the Director

<http://www.nih.gov/icd>

National Institute
on Aging

National Institute
on Alcohol Abuse
and Alcoholism

National Institute
of Allergy and
Infectious Diseases

National Institute
of Arthritis and
Musculoskeletal
and Skin Diseases

National Cancer
Institute

National Institute
of Child Health
and Human
Development

National Institute on
Deafness and Other
Communication
Disorders

National Institute
of Dental and
Craniofacial
Research

National Institute
of Diabetes and
Digestive and
Kidney Diseases

National Institute
on Drug Abuse

National Institute
of Environmental
Health Sciences

National Eye
Institute

National Institute
of General
Medical Sciences

National Heart,
Lung, and Blood
Institute

National Human
Genome Research
Institute

National Institute
of Mental Health

National Institute
of Neurological
Disorders and
Stroke

National Institute
of Nursing Research

National Center on
Minority Health
and Health
Disparities

National Center
for Complementary
and Alternative
Medicine

Fogarty
International
Center

National Center
for Research
Resources

National Library
of Medicine

National Institute
of Biomedical
Imaging
and
Bioengineering

Largest SBIR/STTR
set-asides



NIH ISSUES MULTIPLE SOLICITATIONS

1. SBIR/STTR Omnibus Grant Solicitation (NIH, CDC, and FDA) = Parent FOA

Release: January April 1, Aug 1, Dec 1 receipt dates

2. SBIR Contract Solicitation (NIH, CDC)

Release: August November 6, 2006 receipt date

3. NIH Guide for Grants and Contracts

Release: Weekly Various receipt dates

<http://grants.nih.gov/grants/funding/sbir.htm>

NIH SBIR/STTR RESEARCH AREAS

Our Ideas.... examples

Biodefense

Biosensors

Nanotechnologies

Bioinformatics

Behavioral research

Computational Biology

Telehealth

Biosilicon devices

Biocompatible **materials**

Acousto-**optics** / opto-**electronics**

Imaging technologies

Genetically engineered proteins

Proteomics / Genomics

Complementary & Alt. Med (CAM)

...

NIH SBIR/STTR RESEARCH GRANT TOPICS

Your

- *Invest*
- *Rese*
- *“Oth*
mis
- *...*

Angioscopes
to
Zebrafish

Take-home Message #2

Parent SBIR FOA

PA-06-120: PHS 2006-02 Omnibus Solicitation of the NIH, CDC, and FDA for Small Business Innovat - Microsoft Internet Explorer

File Edit View Favorites Tools Help

Back Forward Stop Home Search Favorites RSS Print Mail News Groups

Address <http://grants.nih.gov/grants/guide/pa-files/PA-06-120.html> Go

Google Search PageRank 826 blocked Check Look for Map AutoFill Options

Title: PHS 2006-02 Omnibus Solicitation of the NIH, CDC, and FDA for Small Business Innovation Research Grant Applications (Parent SBIR [R43/R44])

Announcement Type

New (See [PA-06-06-006](#) and [PA-06-007](#) for previous [now expired] SBIR and STTR Parent announcements.)

NOTICE: Applications submitted in response to this Funding Opportunity Announcement (FOA) for Federal assistance must be submitted electronically through Grants.gov (<http://www.grants.gov>) using the SF424 Research and Related (R&R) forms and the SF424 (R&R) SBIR/STTR Application Guide. **APPLICATIONS MAY NOT BE SUBMITTED IN PAPER FORMAT.**

This FOA must be read in conjunction with the application guidelines included with this announcement in [Grants.gov Apply for Grants](#) (hereafter called Grants.gov/Apply).

A registration process is necessary before submission and applicants are highly encouraged to start the process at least four weeks prior to the grant submission date. See [Section IV](#).

Two steps are required for on time submission:

- 1) The application must be submitted to [Grants.gov](#) by 5:00 p.m. local time (of the applicant institution/organization) on the submission date (see "[Key Dates](#)" below).
- 2) Applicants must complete a verification step in the eRA [Commons](#) within two (2) business days of notification from NIH. Note: Since email can be unreliable, it is the responsibility of the applicant to periodically check on their application status in the [Commons](#).

This FOA is for the standard NIH, CDC, and FDA SBIR submission dates of April 1, 2006, August 1, 2006, and December 1, 2006 and for NIH AIDS/AIDS-related application submission dates of May 1, 2006, September 1, 2006, and January 2, 2007.

Program Announcement (PA) Number: PA-06-120

[Apply for Grant Electronically](#)

For Assistance downloading this or any Grants.gov application package, please contact Grants.gov Customer Support at <http://grants.gov/CustomerSupport>

Catalog of Federal Domestic Assistance Number(s)

93.061, 93.063, 93.067, 93.103, 93.113, 93.114, 93.115, 93.118, 93.121, 93.135, 93.136, 93.143, 93.161, 93.172, 93.173, 93.184, 93.185, 93.197, 93.206, 93.208, 93.213, 93.233, 93.242, 93.262, 93.268, 93.273, 93.279, 93.283, 93.286, 93.307, 93.361, 93.389, 93.393, 93.394, 93.395, 93.396, 93.399, 93.837, 93.838, 93.839, 93.846, 93.847, 93.848, 93.849, 93.853, 93.855, 93.856, 93.859, 93.865, 93.866, 93.867, 93.879, 93.941, 93.942, 93.943, 93.947, 93.978

Done Internet

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NIH Guide for Grants & Contracts

Special SBIR/STTR Opportunities

NIH: Grants & Funding Opportunities - Netscape

File Edit View Go Communicator Help



Bookmarks Location:
WebMail Radio F

<http://grants.nih.gov/grants/guide/index.html>

NIH Guide for Grants and Contracts

On This Page

- NIH Guide LISTSERV
- NIH Guide Archives
- Search NIH Guide
- NIH Guide Description
- Other Information
- Contacts

On OER Site

OER Home
Welcome
News
NIH Guide
Grant Topics
Research Training
Related Topics

Welcome to the NIH Guide - Articles ma

- Going directly to Articles using one of the two Cor
- Searching the Guide Archives below using key wo
- Subscribing to the weekly content notifications via

Comprehensive Archives of Published N

- By Year and Week Ending:
[2001](#) [2000](#) [1999](#) [1998](#) [1997](#) [1996](#)
- By Announcement Category:
[Notices](#) [Program Announcements](#) [Regu](#)

Search the NIH Guide (Enter keywords or phrases, separat

SBIR and Publication_Date>=01/01/2001

Search the NIH Guide

Clear

(Maximum of 1000 Results per Query)

Search Tips:

Case: ALL UPPER or all lower = Not case sensitive

Mixed Case = Case sensitive except when in quotes

Title only search: Title <contains> "search string"

Keyword only search: Keywords <contains> "search string"

Volume/Issue search: Volume=X and Number=Y and "search string"

On or After Specified Publication Date: (Publication_Date >= 10/01/2000) and "search string"

Publication Date Range: (Publication_Date >= 01/01/2000 and Publication_Date <= 12/31/2000)

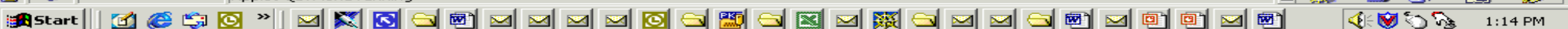
For more options and to search other areas, try the [Advanced Search](#)

Go Beyond the
SBIR/STTR Omnibus
Solicitation....

[Search Help](#)



Applet QLTMenu running



Grant Application Process

Are you R  ady?

Submitting an Application Electronically

- Find out at <http://era.nih.gov/ElectronicReceipt/>.
- New electronic Grants.gov application SF424 (R&R)
 - Check the Timeline
 - Register EARLY... <http://grants.gov/>

Electronic Submission Information:

<http://era.nih.gov/ElectronicReceipt/>



OER Home

NIH Electronic Research Administration

Electronic Submission of Grant Applications

- [Home](#)
- [Drivers for Change](#)
- [Electronic Submission Timeline](#)
- [Preparing for Electronic Submission](#)
- [Applying through Grants.gov](#)
- [Electronic Submission FAQ](#)
- [Related NIH Guide Notices](#)
- [Service Providers](#)
- [Communication Resources/Outreach](#)
- [Support](#)
- [Links](#)
- [History of Electronic](#)

Electronic Submission

Big changes are coming to grants submission at the National Institutes of Health and the Agency for Healthcare Research Quality. Both NIH and AHRQ will soon **require** all competing research grant applications to come in **electronically** via the web portal of Grants.gov on a new SF 424 Research and Related (R&R) application.

We are phasing in the changes by type of grant program (mechanism), beginning with the Dec. 1, 2005 submission date for small business (SBIR/STTR) applicants and culminating in May 2007 when all grant programs will be submitted electronically on the new form [see [Transition Plan](#)].

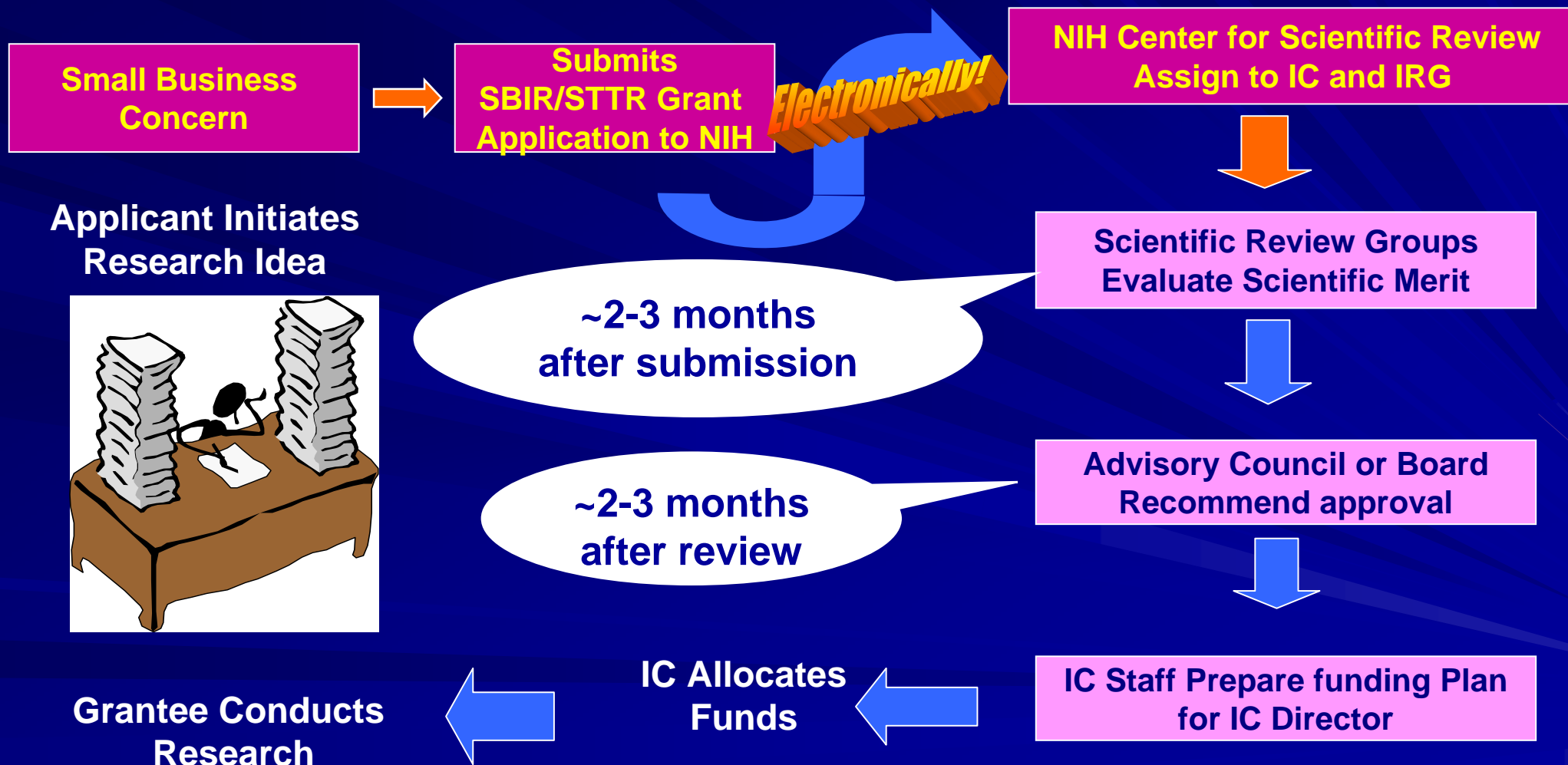
Applicants should carefully note the transition date for the grant mechanism for which they wish to apply.

- Once a grant mechanism is transitioned to the electronic mode and the grant opportunity is posted on Grants.gov, applicants will be able to download and begin working on their application package. For instance, if a grant opportunity is posted Oct. 17, applicants will be able to download and begin working on the application package on or after Oct 17. However, they cannot submit the application until the funding opportunity's open date. That grant opportunity may have an open date of Nov. 7 for a Dec. 1 submission deadline. In that case, the applicant can submit an application electronically to Grants.gov any time between the open and submission dates, i.e. any time between Nov. 7 and Dec. 1.
- An applicant must be cognizant of the fact that until a grant mechanism is transitioned, any

**NIH is ready for
Electronic
Submission.
Are You?**

[Find out where to register](#)

NIH Small Business Program Review Process



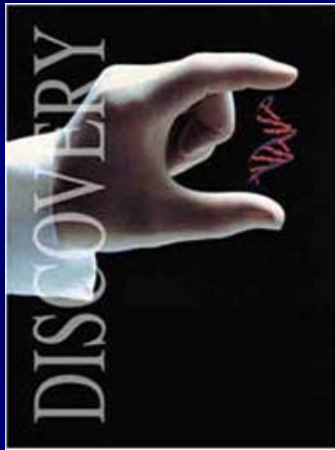
Applications Submitted to NIH Center for Scientific Review

REGARDLESS OF INSTITUTE/CENTER TOPIC “LINKAGE”

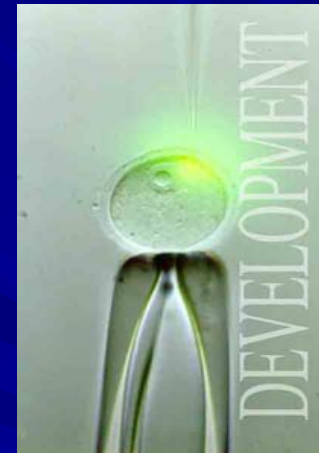
Cover Letter: A Valuable Tool

- **Suggest potential awarding component(s)**
- **Discuss areas of expertise appropriate for the application's review**
- **Indicate individual(s) or organization(s) in conflict**

Gap Funding Options



Phase I



Phase II

NIH SBIR/STTR Program

Gap Funding Options

- **Phase I / Phase II Fast Track**
 - **Simultaneous submission / concurrent review**
- **No-Cost Extension (Ph I or Ph II)**
 - **Extension in time with no additional funds**
- **Administrative / Competitive Supplements**
- **Phase II Competing Renewal**
 - **Maximum of \$1M/yr for 3 years**
 - **Response to program announcement**

NIH SBIR/STTR FAST-TRACK

Bridging the Phase I - II Funding Gap

Phase I + Phase II
(Simultaneous Submission
and Concurrent Review)

7-9 months



Phase I Award

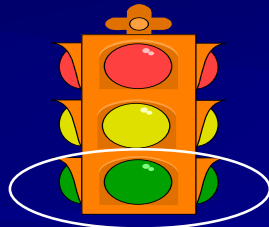
Completion of Phase I

Phase I Final Report



Program Staff assess
completion of specific aims
and milestones

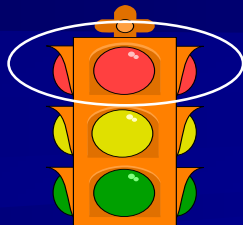
Go / No Go?



Aims/ Milestones
Met



Phase II award



Aims/ Milestones
NOT Met



Phase II award

Grant Application Assignment:

**What if I cannot
determine which IC is
most appropriate?**

Application Assignments



Institutes/Centers

NIH Center for Scientific Review
RECEIPT and REFERRAL STAFF refer applications to Institute or Center as the potential **funding component**:

- Match between research proposed and IC's mission
- Multiple IC assignments when technologies cross-cut more than one IC



Scientific Review Groups

NIH Center for Scientific Review
RECEIPT and REFERRAL STAFF refer applications to an Initial Review Group and Study Section:

- Match between research and scientific review group within IRG
- Scientific expertise/specialization
- Special Emphasis Panels
Ad hoc; Not Chartered

Review Considerations

Selection Criteria

- **External** peer reviewers (academia / industry)-- scientists and engineers determine the merit of a proposal.
- All applicants receive “debriefing” automatically.
- **Evaluation factors:**
 1. Significance (Real Problem/Commercial Potential)
 2. Approach (Research Design, Feasible)
 3. Innovation (New or Improved?)
 4. Investigators (PI and team)
 5. Environment (Facilities/Resources)
 - ... **Protection of Human Subjects**
 - ... **Animal Welfare**
 - ... **Budget**

**Program staff do
NOT participate
in peer review
process**

HINT!

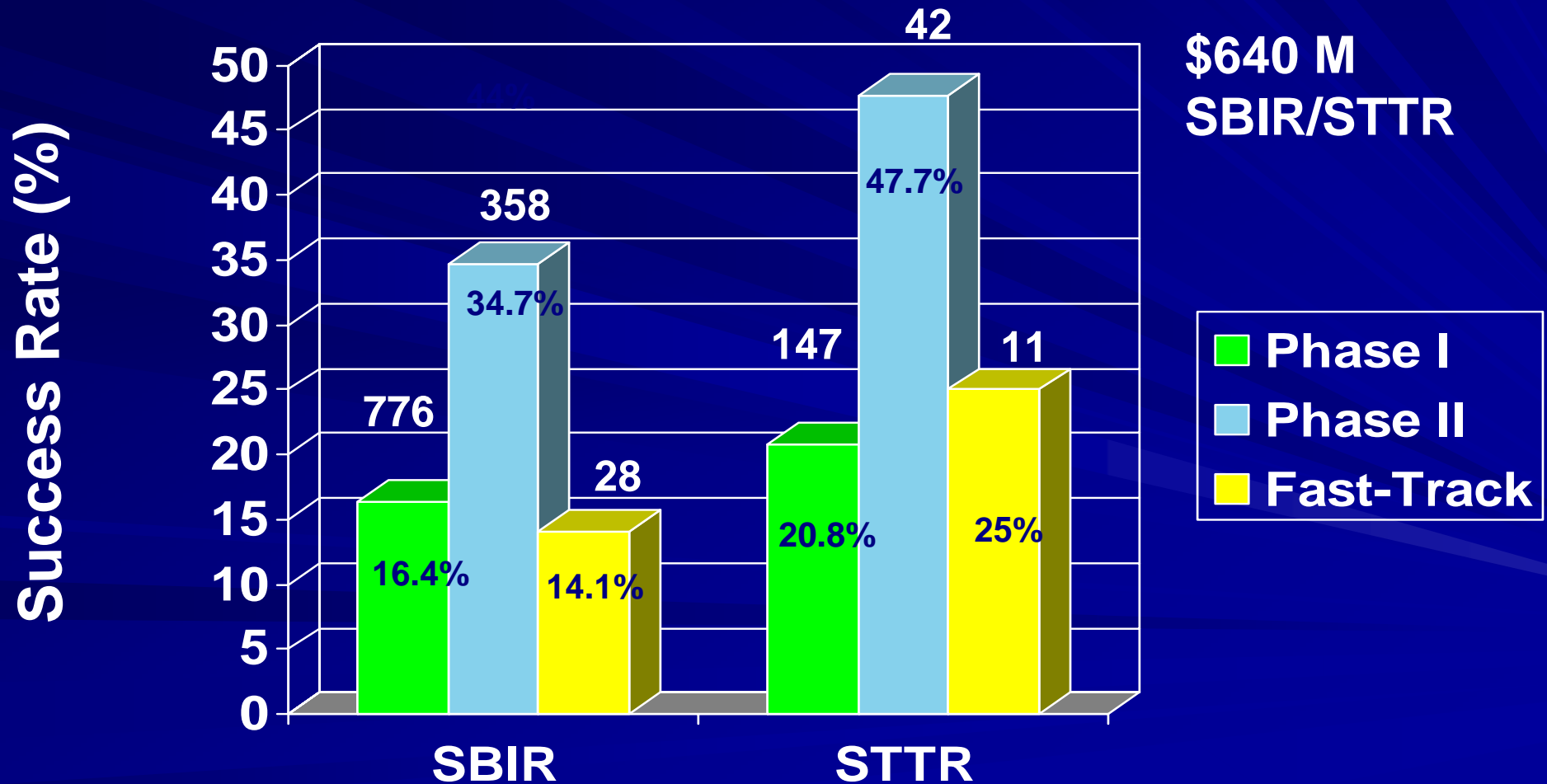
**Research Plan should include answers
to questions described under Review
Criteria!**

(See Solicitation)

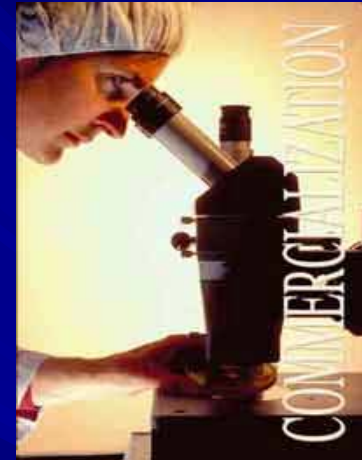
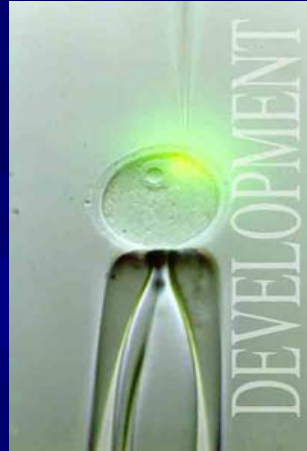
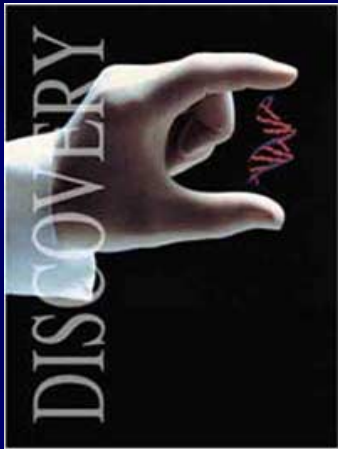
Common Problems with Applications

- Inadequately defined test of feasibility
- Diffuse, superficial, or unfocused research plan
 - Lack of sufficient experimental detail
- Questionable reasoning in experimental approach
 - Uncritical approach
 - Failure to consider potential pitfalls and alternatives
- Lack of innovation
- Unconvincing case for commercial potential or societal impact
- Lack of experience with essential methodologies
- Unfamiliar with relevant published work
- Unrealistically large amount of work proposed

NIH SBIR/STTR FUNDING RATES FISCAL YEAR 2005



Transitioning SBIR / STTR Projects to the Marketplace



Phase I



Phase II



Phase III



Technical Assistance Programs

Commercialization Assistance

(Phase II awardees)

Business & strategic planning

Builds alliances and investor partnerships

Niche Assessment

(Phase I awardees)

Identify other uses of technology

Determines competitive advantages

Develops market entry strategy

Competing Continuation Phase II Award

Purpose

- To take **existing, promising compounds** developed under a **Phase II** through the **next step** of drug discovery and development.
- Provide additional Phase II **research support** to continue assessing and improving devices or conducting preclinical studies of drugs or devices that ultimately require:
 - ❖ clinical evaluation
 - ❖ approval of a Federal regulatory agency
 - ❖ refinements to durable medical equipment (DME) designs

Competing Continuation Phase II Award

Eligibility

- SBIR Phase II awardee:
- Promising pharmacologic agents or devices have already been identified (or developed) and some preclinical pharmacology has been conducted.
- Response to an NIH Program Announcement
- Generally, \$750k-\$1M/year for up to 3 years

Contact your Program Director to discuss!

For More Information
www.nih.gov

<http://grants.nih.gov/grants/funding/sbir.htm>

Jo Anne Goodnight

NIH SBIR/STTR Program Coordinator

Phone: 301-435-2688

Email: jg128w@nih.gov

Kay Etzler

SBIR/STTR Program Analyst

Phone: 301-435-2713

Fax: 301-480-0146

Email: etzlerk@od.nih.gov

Kathleen Shino

SBIR/STTR Program Specialist

Phone: 301-435-2689

Fax: 301-480-0146

Email: shinok@mail.nih.gov

<http://grants.nih.gov/grants/funding/sbir.htm>



Small Business Funding Opportunities

[OER Home](#)

[Funding Opportunities](#)

[Applications & Forms](#)

[Awarded Grants](#)

[Grants Policy](#)

[A](#)

[Out OER](#)

News Flashes [\(Current\)](#), [2004 Archive](#), [2003 Archive](#)

- **NEW** Six Additional CDC Topics have been added to the
- [NIH 2005 SBIR Contract Solicitation has been Amended](#)
- [2005 SBIR Contract Solicitation Now Available](#)
- [All Federal wide Assurances \(FWAs\) expire 3 years](#)
- [Presentations from the 6th Annual NIH SBIR/STTR Conference](#)
- [Use of Current PHS 398, 2590 and Related Forms \(CER\)](#)
- [Executive Order 13329 -- Encouraging Innovation in Medicine](#)
- [The NIH Commons -- NIH is Stepping Closer to Its Goals](#)
- [PHS 2004-2 Omnibus Solicitation for Phase I SBIR/STTR Grants](#)
- [UPDATED Instructions for Phase II SBIR/STTR Grants](#)

Contents

- [Small Business Innovation Research \(SBIR\) and Small Business Technology Transfer \(STTR\) Grants](#)
- [Solicitations for SBIR/STTR Grant Applications and Solicitations](#)
- [Forms and Instructions](#)
- [Sample SBIR Applications](#)
- [Special Announcements for Small Business Research Opportunities](#) **UPDATED** - [Subscribe to the weekly content notifications via email using the NIH Guide Table of Contents Notification LISTSERV service.](#)
- [Collaboration Opportunities and Research Partnerships \(CORP\)](#) **UPDATED**
- [Receipt Dates](#)
- [SBIR/STTR Review Criteria](#)
- [SBIR/STTR Award Data](#)
- [SBIR/STTR Policy and Grantsmanship Information](#)
- [Invention Reporting Requirements](#) - Letter to SBIR/STTR Award Recipients

- Alerts/News Flashes
- Solicitations
- Targeted Research Opportunities
- Award Information
- Collaborative Opportunities
- Success Stories
- Resources

Stay Informed...

List serves

- NIH Guide for Grants and Contracts (weekly notification)

<http://grants.nih.gov/grants/guide/listserv.htm>

- NIH SBIR/STTR Notification

<http://grants.nih.gov/grants/funding/listserv.htm>

FINDING A PARTNER

- **CRISP Award Database**

<http://crisp.oit.nih.gov>

- **NIH Collaboration Opportunities and Research Partnerships**

<http://grants.nih.gov/grants/funding/corp.htm>

- **NIH Office of Technology Transfer**

<http://ott.od.nih.gov/>

RESOURCES

A GOOD STARTING POINT

- NIH Small Business Funding Site

<http://grants.nih.gov/grants/funding/sbir.htm>

- Computer Retrieval of Information on Scientific Projects (CRISP)

<http://crisp.cit.nih.gov>

- Contacts at NIH

<http://grants.nih.gov/grants/contacts.htm>

- National SBIR/STTR Resource Center

<http://www.sbirworld.com>

RESOURCES

HOW TO WRITE A GRANT APPLICATION

Grant Application Preparation

http://grants1.nih.gov/grants/grant_tips.htm

http://grants1.nih.gov/grants/funding/sbir_policy.htm

<http://www.niaid.nih.gov/ncn/grants/>

<http://deainfo.nci.nih.gov/EXTRA/EXTDOCS/gntapp.htm>

<http://www.nlm.nih.gov/ep/Tutorial.html>

NIH Success Stories

CardiacAssist, Inc. (PA)



TandemHeart® PTVA® (Percutaneous Transseptal Ventricular Assist) System

LIGOCYTE®
PHARMACEUTICALS, INC.

LigoCyte has developed a **monoclonal antibody** capable of **inhibiting inflammatory disease** in the lung.

TissueTech (FL)

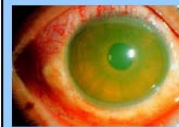


Spotlight!

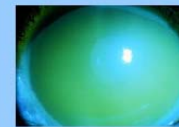
Amniotic Membrane Transplantation
For Acute Chemical Burn

CLINICAL PRESENTATION

Before

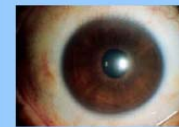


Before



SURGICAL OUTCOME

After



After



KEY SURGICAL STEPS

1. Lay down amniotic membrane to cover the entire corneal and conjunctival surfaces with the stromal side facing down
2. Secure AM to the lid margin by interrupted or 9-0 or 10-0 Vicryl suture the membrane to the lid margin
3. Tug the membrane to the fornix with a muscle hook and secure it with 4-0 Silk double arm matrix suture to the skin with a bolster

Intralase Corporation (CA) Corneal Surgery with Femtosecond Lasers



**I'm from the
Government, and
I'm here to help
you....**

National Institute
on Aging



National Institute
of Diabetes and
Digestive and
Kidney Diseases



National Institute
of Environmental
Health Sciences



Fogarty
International
Center

National Cancer
Institute



National Institute
of Dental and
Craniofacial
Research

National Eye
Institute



National Institute
on Drug Abuse

National Institute
of Child Health
and Human
Development

NIAAA

National Institute
of Biomedical
Imaging
and
Bioengineering

NIBIB



National Institute
of Arthritis and
Musculoskeletal
and Skin Diseases

National Institute
of General
Medical Sciences

National Institute
of Mental Health



National Human
Genome Research
Institute



National Institute on
Deafness and Other
Communication
Disorders



National Institute
of Neurological
Disorders and
Stroke



National Center on
Minority Health
and Health
Disparities

National Institute
on Alcohol Abuse
and Alcoholism



NIDCD

National Heart,
Lung, and Blood
Institute



National Library
of Medicine



National Institute
of Allergy and
Infectious Diseases



National Center
for Research
Resources

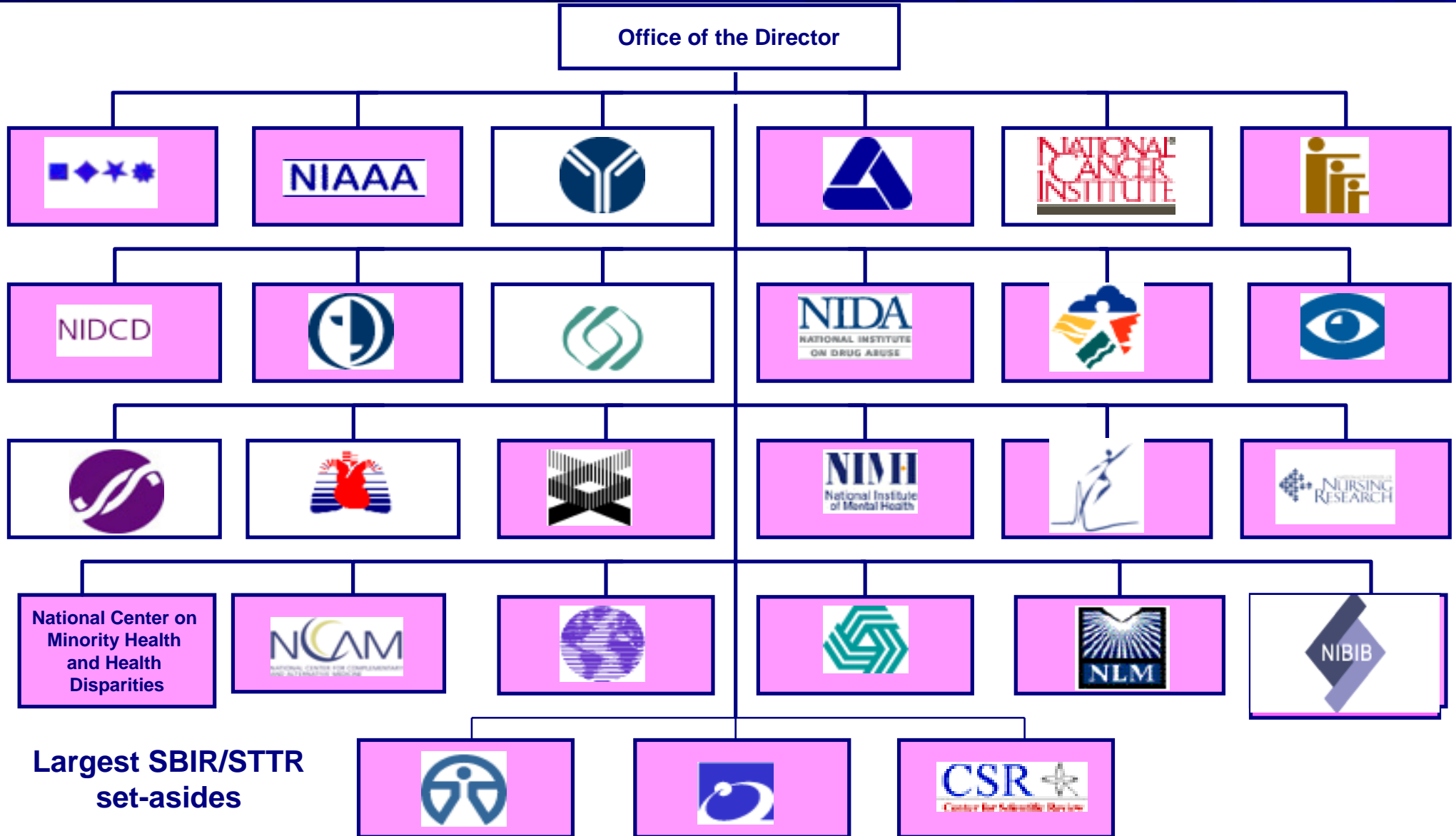
Largest SBIR/STTR
set-asides

National Center
for Complementary
and Alternative
Medicine

New!

National Institutes of Health

<http://www.nih.gov/icd/>



Thank You